OCT 1 0 2000

K002140

510(k) Summary

Applicant's Name and Address: Menicon Co., Ltd.
21-19, Aoi 3-Chome
Naka-ku, Nagoya 460-0006
Japan

Contact Person: Mitsuo Yajima
Phone 011 81 52 935 1676
Fax 011 81 52 935 1633

Summary Prepared July 2000

Trade Name:

Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses

Classification Name:

rigid gas permeable contact lens solution

Common/Usual Name

periodic cleaner

Predicate Device:

Allergan ProFree/GP® Weekly Enzymatic Cleaner

Device Description:

Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses consists of two solutions, Progent A and Progent B, which are mixed together when used. They are packaged separately in natural low density polyethylene (USP classification :VI) ampoules, type "Bottle Pack", containing 5.5 ml of solution, (5 ml being usable). Each package consists of 7 pairs of ampoules.

Progent A contains sodium hypochlorite and sodium carbonate;
Progent B contains potassium bromide and sodium carbonate.
Rigid Gas Permeable Contact Lenses are placed into the lens holder cap of the cleaning vial (SP Vial). Progent A, then Progent B are poured into the case receptacle, then the lenses are soaked in the Progent mixture for 30 minutes.

Indication for Use:

Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses, when used as directed, cleans and removes protein deposits from fluorosilicone acrylate rigid gas permeable contact lenses.

Substantial Equivalence:

The claim of substantial equivalence to Allergan ProFree/GP is based on the indication for use as a periodic cleaner, which removes protein from rigid gas permeable contact lenses.

The applicant performed non-clinical stability, toxicology, microbiology and compatibility testing which supports the claim of substantial equivalence to Allergan ProFree/GP.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 0 2000

Ms. Beverley D. Venuti, Ph.D., R.A.C.
Staff Consultant
Forestsight Regulatory Strategies
269A Ballardvale Street
Wilmington, MA 01887

Re: K002140
Trade Name: Menicon Progent Remover
Regulatory Class: II
Product Code: MRC
Dated: 13 July, 2000
Received: 17 July, 2000

Dear Ms.Venuti:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K002140

Device Name: Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses

Indications for Use:

Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses, when used as directed, cleans and removes protein deposits from fluorosilicone acrylate rigid gas permeable contact lenses.

This cleaning system is for professional in-office use only.

(Please do not write below this line. Continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Lauel W. C. Brown, Ph.D.

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K002140

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 80.109)

(Optional Format 1-2-96)